



**AusBiotech submission in response to the
*Prostheses List Reforms - Consultation Paper 3 -
A modernised fit-for-purpose listing process***

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Introduction

AusBiotech welcomes the opportunity to submit a response to the Department of Health's (DoH) consultation paper on a modernised fit-for-purpose Prostheses List (PL) listing process (Consultation Paper No. 3, published 14 January 2022). Concurrently, a Proposal for a Cost Recovered Pathway for Medical Services Advisory Committee (MSAC) Applications has been issued for consultation, which is relevant for the PL listing process and therefore also considered in this response. This submission represents AusBiotech members actively engaged in delivering economic benefits to Australia through the commercialisation of biotechnologies and medical technologies – in particular those developing products that are and will be listed on the PL.

AusBiotech is a well-connected national network of over 3,000 members in the life sciences industry, which includes medical technology, bio-therapeutics, and agricultural biotechnology sectors. The sector employs in excess of 290,000 Australians and industry consists of more than 1,300 biotechnology companies. About 80 per cent of these industry companies are classified as small to medium enterprises (SMEs) and are working to commercialise their research.

In Australia, with a few exceptions, these companies are typically young and small, competing globally for investment and market share. Typically, the research, publicly-funded in hospitals, universities or medical research institutes, or privately developed by surgeons, should it show promise as an implantable device, enters a translation process that relies on the attraction of private capital. The Australian Government relies on this public/private compact to bring products to patients/market.

The task ahead, in the Australian context, is to leverage the intellectual property (IP) rights and attract the hundreds of millions of dollars required over the five or more years of the clinical trials and development that it takes to reach regulatory approval. While the PL is often thought to be applicable only to multinational companies, AusBiotech members are typically SMEs and are locally developing new technologies, many of which will be destined for potential inclusion on the PL. Many of these companies have one or a few devices in development, and some are manufacturing in Australia too.

Australia is home to a world-class medical and health research ecosystem and if it cannot be commercialised, it cannot reach the ultimate beneficiaries: the Australian community.

Key comments on Consultation Paper No. 3 & MSAC Cost Recovery

On behalf of its members representing the Australian life sciences industry, AusBiotech appreciates the opportunity to provide comments on the proposed PL listing pathways. As an integral part of the PL Reform, the listing pathways must ensure fit-for-purpose processes to ensure timely access for private health insurance members to medical device innovation. Key comments on Consultation Paper No. 3 are:

- Retain a standing consultative stakeholder mediating body, like the current Prostheses List Advisory Committee (PLAC), to ensure a balance of interests for final decision making in all three proposed listing pathways by providing consistent and coherent PL listing advice to the Minister.
- Implement parallel process of TGA approval and PL submission assessment for all three listing pathways.

- Remove the requirement for all Class III devices to go through a focused HTA, and determine the appropriate listing pathway based on the type of clinical and economic claims rather than TGA device classification.
- Consistent with other Government policies and programs, reward local innovation by reducing or refunding cost recovery fees of all three listing pathways for PL applications of medical devices backed with Australian innovation.
- Ensure process is predictable through clear and mutually exclusive listing pathway criteria and guidelines for applications, as well as pre-listing consultations.
- Increase transparency around listing decisions by publishing application summary documents.
- Manage post-listing monitoring and PL de-listings via clear and transparent criteria.
- Timelines and milestones for all three listing pathways must be clearly defined, predictable and reflective of the varying complexity of the three pathways to PL listing.

Background

In the 2021-2022 Budget, the Australian Government announced its commitment to reform the PL. The purpose of the reform was to improve access to medical devices and make sure it is efficient, transparent, and keeps up with technological advances. The reform implementation would seek to limit the scope of prostheses to primarily implantable devices, minimise any differences between public and private health insurance (PHI) pricing, simplify the PL through the regrouping of devices and improving listing pathways to ensure more streamlined and “fit-for-purpose” assessment and decision making.

As well as containing cost, PL Reform is an opportunity to reflect the Australian Government’s objectives to drive domestic innovation¹ and effort in the medical device sector and to address the ongoing shortcomings of PL listing medical devices under PHI. It is an opportunity to deliver reform that drives Australian domestic innovation and ensures domestic research and development (R&D) to be commercialised more quickly both in Australia and globally.

Principles to drive innovation in Australia’s medical devices industry through PL Reform

AusBiotech proposes five key principles for the DoH to consider in a re-design of current PL listing pathways to ensure improvements are in line with the Australian Government’s whole-of-government approach to innovation.

This reflects AusBiotech’s member feedback on requirements to incentivise domestic medical device innovation, particularly of small and medium-sized Australian companies. The principles seek to optimise timely delivery of technological advancement within the private health system whilst ensuring medical devices deployed under PHI delivers services that are safe, effective and cost-effective for both the Government and Australian patients.

While AusBiotech is pleased that Consultation Paper No. 3 (Consultation Paper) outlines PL improvements that are aligned with these guiding principles, several issues were identified within the proposed listing pathways paper, which may lead to unintended consequences. These issues are further detailed in the context of AusBiotech’s guiding principles below.

¹ <https://www.minister.industry.gov.au/ministers/karenandrews/media-releases/13-billion-modern-manufacturing-initiative-opens-medical-products>

Principle 1: Maintaining safety and efficacy

AusBiotech continues to support Australia's robust regulatory system to deliver safe and effective medical devices. Therapeutic Goods Administration (TGA) processes are robust, rigorous and necessary to ensure medical devices are well manufactured, safe and deliver on their claims. There should be no erosion of these fundamental principles.

Nevertheless, it is important to note that separate discussions and initiatives are underway to streamline TGA processes to ensure more expeditious marketing approvals and global benchmarking. It is important that improvements within TGA processes and PL listing pathways are aligned and planned to maintain predictability of these interlinked approval steps for Australian medical device companies.

AusBiotech notes that the Tier 1 and Tier 2 pathways do not include the final appraisal and decision-making step of consultation through a consultative stakeholder mediating committee, like the PLAC. The role of PLAC as a 'clearing house', made up of a range of stakeholders from clinicians and peak body groups, provides a balance of interests and an opportunity to examine a preliminary recommendation before finalising views for the delegate or Minister. While the final listing recommendation to the Minister or Minister's delegate is made by MSAC in a Full HTA Pathway, in the Clinical/Focused HTA and Abbreviated pathways, the recommendation to the Minister is proposed to be made by the DoH or clinical/economic experts. AusBiotech is of the view that an independent committee like PLAC is essential to ensuring consistency and a balance of views is reflected in the process, particularly regarding HTA decision-making on comparative safety, efficacy and cost-effectiveness. Retaining a consultative stakeholder mediating body, like PLAC, to appraise Tier 1 and Tier 2 applications and their evaluations, and advise MSAC on PL-specific queries if required, ensures consistent and coherent PL listing advice to the Minister.

Recommendation

Retain a standing consultative stakeholder mediating body, like the current PLAC, to ensure a balance of interests for final decision making in all three proposed listing pathways by providing consistent and coherent PL listing advice to the Minister.

Principle 2: Streamlining and efficiency

PL listing pathways should not duplicate existing processes required and decisions made by other agencies within the Australian Government, including the TGA and the MSAC. If the TGA has determined a device is safe and effective, the PL should not allow a parallel process to duplicate, re-examine or question actions or decisions of the TGA. Similarly, where a procedure has an established Medicare Benefits Schedule (MBS) item, or there is a separate parallel process that is already reviewing an MBS item, the PL listing pathways should have confidence other government processes will deliver robust and reasoned outcomes and not duplicate or re-prosecute.

One of the purposes of the Abbreviated Pathway is to potentially reduce the time for an application to be assessed and listed on the PL. However, in contrast, the proposed Abbreviated Pathway does not allow for a parallel application process with regulatory assessment by the TGA. No rationale has been provided to why the Abbreviated Pathway has been deemed unsuitable for a parallel process. Given that the Abbreviated Pathway is intended to reduce red tape and accelerate PL listing for low to medium risk 'me-too' devices, the requirement for inclusion on the Australian Register of Therapeutic Goods (ARTG) before an application for PL listing may be lodged is counterintuitive. AusBiotech would be willing to provide worked case-study examples based on existing technologies

directly to the department that indicate that by assessing regulatory and reimbursement applications sequentially, device manufacturers may be delayed up to six months for devices that clearly qualify for the abbreviated pathway. Moreover, with assessment costs being cost recovered, a submission is at risk for the sponsor, should they choose to submit under parallel process.

AusBiotech recommends the DoH provide a parallel process for all three application pathways to fulfill the principle of improved efficiencies and timeliness for PL listings.

Of further concern is the apparent exclusion of any Class III devices from the Abbreviated Pathway. The TGA Class III designation includes a range of devices and software and there are many examples of applications for Class III devices which would not necessitate a Clinical/Focused HTA Pathway assessment. These include requests for cost-minimised devices to be included in the PL under an existing group, amendment requests for device updates or software upgrades and other applications without financial implications to the PL. AusBiotech is concerned that a blanket exclusion of any applications concerning Class III devices from the Abbreviated Pathway will impede the intended purpose of increased efficiencies and time to listing improvements of the PL Reform. Further, the requirement for all Class III devices to require at least a focused HTA, lacks any policy reasoning or rationale, particularly as every device requires assessment and listing under the TGA. It is not clear from the consultation paper why Class III devices have been proposed to go through a focused HTA.

Recommendation

Implement parallel process of TGA approval and PL submission assessment for all three listing pathways.

Remove the requirement for all Class III devices to go through a focused HTA, and determine the appropriate listing pathway based on the type of clinical and economic claims rather than TGA device classification.

Principle 3: Rewarding innovation and effort

The PL should reflect the Australian Government's objectives to drive domestic innovation and effort, particularly in the medical device sector. The Government already has a growing range of programs, including the Modern Manufacturing Initiative², Medical Research Future Fund³, the proposed Patent Box⁴, the R&D Tax Incentive⁵ and various clinical trial programs⁶ which contribute to the desire for expeditious commercialisation of medical devices. The Government's recent announcement on 2 February to establish an Australian Economic Accelerator (AEA) with a \$2.2 billion package to focus the commercialisation of the six national manufacturing priority areas, including medical products, demonstrates the Government's commitment to deliver domestic innovation and expedite the commercialisation of Australian clinical research. A key component of delivering this is to ensure all aspects of government policy is aligned, including PL Reform. These

² <https://www.industry.gov.au/news/modern-manufacturing-initiative-and-national-manufacturing-priorities-announced>

³ <https://www.health.gov.au/initiatives-and-programs/medical-research-future-fund>

⁴ <https://www.ato.gov.au/General/New-legislation/In-detail/Direct-taxes/Income-tax-for-businesses/Patent-Box---tax-concession-for-Australian-medical-and-biotechnology-innovations/>

⁵ <https://business.gov.au/grants-and-programs/research-and-development-tax-incentive>

⁶ <https://www.nhmrc.gov.au/funding/find-funding/clinical-trials-and-cohort-studies-grants>

programs encourage and catalyse domestic innovation and PL Reform should be appropriately calibrated to deliver a similar policy outcome.

The PL is an important policy lever for the Government to encourage technological innovation within the medical device sector, particularly from Australian medical device companies.

Once listed on the PL, medical devices have access to the PHI sector, which covers 46 per cent of Australians and is a critical pillar of Australia's mixed healthcare model. Private health insurance that delivers cutting edge technological innovation and an alternative service offering than under the public system is an essential differentiator for private health members. Delivering the most innovative technological devices in a timely manner benefits patients, private health insurers and medical device industry. Technological innovation underpinned by Australian research, including clinical evidence conducted in Australian clinical trials, should be recognised through a timely awarding of additional benefit, commensurate with superior clinical benefit the medical device delivers.

While cost recovery fees for the PL pathways are yet to be proposed by the DoH, AusBiotech expects these to align with the complexities of the application pathways, noting that the proposed fees for the full HTA pathway undertaken by MSAC have been published in a separate consultation paper. Of note, in the current PL process, several applications (e.g. for amendments of products listed under multiple billing codes) may be submitted and assessed concurrently. It is expected that the cost recovery fee structure will take these procedural circumstances into account and avoid multiple billing for such grouped assessments.

Any cost recovery fees will have to be recouped by companies, increasing the cost differential involved in delivering services through the public and the private system. While making products available in the public system is not associated with a resource intensive listing process and procedural fees, an increase, or in the case of Full HTA by MSAC the introduction of cost recovery fees, will disincentivise PL listings against access through the public system. Given the proposed criteria for the Full HTA pathway, all prostheses evaluated by MSAC would require a Complex Application as per MSAC cost recovery consultation paper. The total minimum fee for this pathway (incl. PICO conformation through PASC) would amount to \$202,760. The revenues collected from cost-recovered application fees should be directly reinvested in the listing process to enable better service delivery in the future. If revenues are returned to consolidated revenues, it does not provide transparency and potentially encourages an escalation of fees in the future without benchmarking to the actual costs of implementing specific pathways.

AusBiotech advocates for prioritisation of domestic Australian incorporated entities. Rebates on cost recovery fees for Australian medical device companies would reward and catalyse domestic innovation and facilitate Australians with PHI to gain early access to these local advancements in medical technology. A similar rebate system has been implemented by Austrade with their Export Market Development Grants (EMDG). Under that regime, if an entity qualifies for a rebate, eligible international marketing activities may be rebated. Similarly, the PL could identify criteria that enabled Australian medical device companies to receive a rebate on the relevant PL application fees. AusBiotech requests the DoH consider implementing a similar administrative instrument to reduce or refund fees for all three pathways for eligible Australian companies.

Recommendation

Consistent with other Government policies and programs, incentivise local companies by reducing or refunding cost recovery fees of all three listing pathways for PL applications of medical devices backed with Australian innovation.

Principle 4: Clarity and transparency

The domestic medical device industry requires clarity and transparency to allow it to appropriately plan and allocate limited financial and human resources. The PL can deliver greater certainty and predictability for all stakeholders by issuing early, clear, non-overlapping guidance criteria for the listing pathways and then setting and committing to timelines for each pathway, with defined milestones for interactions with industry sponsors.

For the proposed listing pathways, it will be essential to identify early the most appropriate, non-overlapping path for evaluation: Abbreviated, Clinical/Focused HTA or Full HTA pathway for their medical device. Distinct criteria for PL listing pathways will provide companies a clearer road to commercialisation, allowing them to identify well in advance the optimal pathway and plan accordingly.

It is disappointing that the Consultation Paper stops short of outlining the specific criteria defining each pathway and only provides limited detail on submission requirements for applicants. The information provided at this stage raises questions and concerns which should be addressed with urgency to provide the medical devices industry an opportunity to comment and assess implications for near future applications.

In order to facilitate efficient entry to any of the pathways, clear guidance with the least possible ambiguity is required. The detailed criteria for the new pathways need to be clear, transparent and mutually exclusive in order to enable industry to plan and prepare their applications accordingly. It is acknowledged that, as outlined in the Consultation Paper, there may be cases where the pathway will change during the assessment. However, this should only occur if circumstances of an application change so that a submission falls into the set-out pathway criteria of a higher (or lower) Tier.

Early – and preferably binding – consultation advice to member companies involved in focused HTA applications deemed the complexity of cost-effectiveness analyses to necessitate a full HTA assessment by MSAC. A clear definition of “focused cost-effectiveness assessment” is sought, noting that a standard economic evaluation (e.g. a cost-utility model) should not require assessment by MSAC. As outlined in the Consultation Paper, AusBiotech agrees that the Full HTA Pathway should only be required for first-in-class/breakthrough technologies with significant financial impact or listings which require establishing or modifying an MBS item. Given that cost-effectiveness is a mainstay of any HTA assessment, the complexity of a modelled evaluation itself should not trigger classification as a full HTA application.

Apart from clear criteria for pathway applicability, guidelines are required explaining in detail the requirements and how to prepare applications for each PL pathway. The guidelines need to provide detailed instructions on what information is required to support a proposed new prosthesis, and the most appropriate form of clinical evidence and economic evaluation for specific submissions.

AusBiotech emphasises that for many Australian innovations, especially for implants and devices used in small populations, direct head-to-head trials often cannot be conducted. As noted by the

MSAC, a variety of other comparative study designs and indirect comparisons with small sample sizes will often constitute the best level of available evidence⁷. The guidelines and decision criteria therefore need to consider varying levels of available comparative evidence to substantiate a superiority claim for a new listing and without unnecessary penalty.

One of the six core principles of a modern listing process specified in the Consultation Paper is balancing transparency and confidentiality. However, the Consultation Paper does not further address transparency and confidentiality. AusBiotech notes the importance of process transparency and confidentiality and proposes the introduction of abbreviated public summary documents for PL applications. Providing information to the public on application claims, evaluation and PL decision making.

Underpinning transparency is clarity around application requirements, timelines and decision criteria as outlined above. Industry requires predictability to plan and prepare applications before and during the process, adding to the efficiency objectives set out by the PL Reform. Submission deadlines and other application milestones should be clearly defined, enabling industry to efficiently apply resources to the listing process.

AusBiotech agrees to mechanisms to regularly monitor the utilisation of PL-listed medical devices. The de-listing process outlined in the Consultation Paper for reasons that a device “*no longer satisfies the criteria for listing or where there are safety concerns or cancellation or suspension of ARTG entry by the TGA*” appears reasonable. However, further guidance and transparency specifically around circumstances in which listing criteria are deemed to be no longer satisfied is sought.

In order to comment on the mechanisms ensuring the PL supports best practice reimbursement (investment) outcomes, detailed information on the scope and triggers for post-market monitoring of reimbursement decisions is required. A transparent and predictable process is crucial for sponsors to maintain oversight on resources required to retain products on the PL. Post-market cost-effectiveness assessments pose the risk of perpetual cycles of HTA given that newer products are deemed cost-effective relative to a comparator on the PL at the time of recommendation.

Recommendation

Ensure process is predictable through clear, binding advice and mutually exclusive listing pathway criteria and guidelines for applications.

Increase transparency around listing decisions by publishing application summary documents.

Manage post-listing monitoring and PL de-listings via clear and transparent criteria.

Principle 5: Timeliness

The domestic medical device industry needs a PL that is agile and nimble – and fit for modern circumstances. Under existing guidelines and lack of clarity on the appropriate listing pathway, a prosthesis might need to go through multiple cycles of clinical and health economic assessment before a final decision is made.

The current Consultation Paper does not outline any proposed timeframes and frequencies (number of cycles per year) for the three evaluation pathways. And while the Consultation Paper does not

⁷ Guidelines for preparing assessments for the Medical Services Advisory Committee V1.0, May 2021

specify the proposed timeline for the Full HTA Pathway undertaken by MSAC, the concurrent consultation paper on the proposed cost recovered pathway for MSAC applications reveals a definite timeframe of 13 months from submission lodgement to receipt of the ratified minutes (incl. PICO confirmation through PASC). These timelines represent a welcome improvement over the current undefined MSAC process duration.

For the “middle” Clinical/Focused HTA Pathway, a significantly faster turnaround than the Full HTA Pathway should be implemented. The fixed PBAC cycle of 17 weeks demonstrates the capability for a full HTA assessment in Australia during that timeframe. Therefore, AusBiotech requests at least three cycles per year be implemented for the Clinical/Focused HTA Pathway. Moreover, a high frequency for Abbreviated Pathway submissions is recommended, ideally with monthly (at a minimum bi-monthly) pathway entry points to allow for timely availability of such devices to Australians with PHI.

Given the differences in assessment durations of the three pathways, it is vitally important for sponsors to be given guidance and clarity to decide which pathway is suitable for each application. The pre-assessment consultation with binding advice such as is provided by Regulatory Authorities should form a basis ahead of any application to maximise clarity and predictability. The importance of planning certainty is compounded by the vastly different time and resources required in preparing applications for the three distinct pathways with varying complexities and requirements for the submission dossiers.

Timelines need to be clear, transparent, adhered to, and where possible, appropriate government resources deployed to ensure timeframes are met and reported on regularly as part of a formal service-level agreement. Timelines cannot be deliberately conservative, but rather designed to assess a medical device as efficiently as possible regardless of the applicable PL listing pathway.

Recommendation

Timelines and milestones for all three listing pathways must be clearly defined, predictable and reflective of the varying complexity of the three pathways to PL listing.